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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/757,295	01/14/2004	Axel Riedel	1/1442	4516

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EXAMINER	
ROYDS, LESLIE A	

ART UNIT	PAPER NUMBER
1614	

MAIL DATE	DELIVERY MODE
05/25/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Advisory Action Before the Filing of an Appeal Brief	Application No. 10/757,295	Applicant(s) RIEDEL ET AL.	
	Examiner Leslie A. Royds	Art Unit 1614	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 11 May 2007 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☐ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☒ The Notice of Appeal was filed on *11 May 2007*. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *2 and 7-18*.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:
    See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

Leslie A. Royds
Patent Examiner
Art Unit 1614

18 MAY 2007

Continuation of 5. Applicant's reply has overcome the following rejection(s):

the objection to the specification and the rejection of claims 2, 7 and 14-17 under 35 U.S.C. 102(b).

Continuation of 11. does NOT place the application in condition for allowance because:
Applicant requests reconsideration of the present application in light of the amendments to the claims and the remarks presented in the papers filed May 11, 2007.

Applicant's arguments against the objection to the specification and the application of the De Gasparo et al. reference under 102(b) will not be further addressed herein because the objection and the rejection have each been withdrawn.

Applicant traverses the rejection of claims 2 and 7-18 under 35 U.S.C. 103(a), stating that De Gasparo et al. fails to teach the claimed combination of telmisartan and atorvastatin anywhere in the reference and, further, fails to teach or suggest that telmisartan increases the expression of genes regulated by the PPARgamma receptor, which is the reason for combining telmisartan with atorvastatin in the presently claimed invention. Applicant additionally asserts that none of the secondary references disclose, suggest or hint at telmisartan combinations with statins.

Applicant's traversal of this rejection has been fully and carefully considered in its entirety, but fails to be persuasive.

Applicant's attention is directed to pages 5-8 of the previous Office Action dated November 27, 2006, which expressly states that De Gasparo et al. clearly contemplates embodiments of the disclosed invention that comprise pharmaceutical compositions of at least two therapeutic components, of which an AT1-receptor antagonist (of which telmisartan is expressly disclosed) or a pharmaceutically acceptable salt thereof and an HMG-CoA reductase inhibitor (of which atorvastatin is expressly disclosed) or a pharmaceutically acceptable salt thereof are expressly disclosed, for the same therapeutic indications as presently claimed. Please reference page 1, line 22 of page 3 and lines 9-11 of page 5 of De Gasparo et al. This teaching is clear and unequivocally speaks to the contrary of Applicant's traversal that the reference does not disclose the claimed combination.

Applicant has again presented the blanket statement that, "...nor does Robl et al., Cecil's Textbook of Medicine, Harlan et al. nor Bohm et al. provide what De Gasparo et al. lacks in providing a motivation, reasonable expectation of success, or teaching or suggestion of all of the claim limitations of the claimed invention. Please see page 5 of Applicant's remarks. This statement of traversal is acknowledged and noted. However, the record clearly indicates that one of ordinary skill in the art would have been motivated to combine the cited references in such a manner to render the presently claimed invention prima facie obvious with a reasonable expectation of success in making such a combination, absent factual evidence or argument to the contrary. Applicant's attention is directed to pages 16-22 of the Office Action dated March 31, 2006, of which said reasons will not be repeated herein so as not to burden the record.

Additionally, Applicant is reminded that rejections made under 35 U.S.C. 103(a) are based upon the combination of references. Accordingly, focusing solely on the discrete teachings of each of the cited references is not persuasive in establishing non-obviousness because it is the combined teachings as a whole that are the basis for a proper conclusion of obviousness. In other words, it must be remembered that the references are relied upon in combination and are not meant to be considered separately as in a vacuum. To properly conclude obviousness of an invention does not require the claimed invention to be expressly suggested in its entirety by any one or all of the references cited under 35 U.S.C. 103(a). Rather the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. Please reference In re Young, 403 F.2d 754, 159 USPQ 725 (CCPA 1968) and In re Keller, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

Applicant further attempts to demonstrate a patentable distinction of the claimed invention over that of the prior art by submitting that neither the primary nor the secondary references teach or suggest that telmisartan increases the expression of genes regulated by the PPAR-gamma receptor, which is the reason that telmisartan is a preferred combination partner for atorvastatin in the treatment of, e.g., diabetes. However, the fact that Applicant has recognized another advantage of the combination of telmisartan and atorvastatin when the prior art already acknowledges the desirability of this same combination for the identical therapeutic objectives as presently claimed cannot be the basis for patentability. Please reference Ex parte Obiaya, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

The explanation of an effect obtained when using a compound cannot confer novelty or nonobviousness on a known process if the skilled artisan was already aware of the occurrence of the desired therapeutic effect. In the instant case, even if De Gasparo et al. did not recognize the advantageous effect on increasing expression of genes regulated by PPAR-gamma when telmisartan and atorvastatin were combined, the fact that Applicant has recognized this advantage is not considered a new therapeutic application because the known treatment of the same diseases as presently claimed using this combination of active agents was already known and recognized in the prior art. Though mechanisms of action of chemical entities are no doubt important contributions to scientific and pharmaceutical development, the assessment of patentability under 35 U.S.C 103 is based upon the therapeutic applications and effects of the compounds, not the mechanism by which they exert such a therapeutic effect.

Accordingly, for these reasons, and those previously made of record in the final rejection of November 27, 2006, rejection of claims 2 and 7-18 under 35 U.S.C. 103(a) remains proper and is maintained.

Applicant states that filing of a Terminal Disclaimer will be considered against the cited copending application(s) if the instant claims are found allowable and if Applicant determines that such an application(s) poses a double patenting issue at that time.

Insofar as the instant claims are not in condition for allowance, and further that the instant claims and the copending claims raise an

issue under the judicially created doctrine of obviousness-type double patenting for the reasons already set forth in the previous Office Action dated November 27, 2006 at pages 8-12, the rejections are maintained.

For these reasons, the claims remain rejected for the reasons of record set forth in the final rejection of November 27, 2006, of which the entirety of said reasons are herein incorporated by reference .

18 MAY 2007

5/22/07

ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER